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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,322	06/07/2001	Ward Beryl Bowen JR.	87312.000003	8426

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/876,322

Applicant(s)
BOWEN et al.

Examiner
John Pak

Art. Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 42-110 is/are pending in the application.
- 4a) Of the above, claim(s) 79 and 83-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 42-78, and 80-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-36 and 42-110 are pending in this application.

Newly submitted claims 79 and 83-110 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These new claims do not require the combination of multivalent metal ion/complex + NAD⁺, as originally presented and claimed. Rather, the new claims require a dehydrogenase + NAD⁺. The newly submitted combination of active agents is distinct. Prior art relevant to multivalent metal ion would not be pertinent to dehydrogenase in the absence of a nexus teaching. Search fields would be divergent and review and consideration of prior art would be divergent.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79 and 83-110 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims **1-36, 42-50, 52-78 and 80-82** will presently be examined to the extent that they read on the originally presented and elected subject matter.

Applicant is advised of the following.

- In claims 3 and 44, the proper nomenclature should be zirconium (IV) EDTA.

Correction as to the placement of the right parenthesis should be made.

- There is no claim 51. All subsequent amendments should be renumbered so that the claim that comes after claim 50 is numbered as 51 and consecutively thereafter.

- Election of species requirement as to the metal ion/complex is hereby withdrawn.

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Claims 1-36 and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 appears to exclude presence of a dehydrogenase, but dependent claims 12-14 seem to require a dehydrogenase. The claims are confusing.

- In claim 1, listing components as “(i)” without any other subsequent itemized components is confusing claim terminology.

- In claim 1, the Markush language “species **including** at least one of a multivalent transition metal ion, **and** a complex thereof” (emphases added) is confusing. First, improper Markush language is used. Proper Markush language is “selected from the group consisting of ... and” Certain variations in language/terminology are acceptable (e.g., “chosen from ...”), but applicant’s variation is not acceptable as it does not clearly define all of the Markush members. Second, the sentence structure, “including ... and ...” implies requiring both the ion **and** a complex thereof. If applicant intended to encompass having just one substance, i.e. just the metal ion or just the metal ion complex, such scope may not be expressed by the present claim language.

Similar language problem is noted in claim 8, 10.

- In claim 2, the proper Markush language is “selected from the [a] group consisting of [including]”

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- In claim 3, “the group consisting of” should be inserted after “selected from” at line 2.
- Claim 6 should be rewritten to recite “further comprising [also] a base.”
- Claim 9 should be rewritten to recite “further comprising”
- Claim 11 should specify which oxidation is meant by “the oxidation.” There are many substances being oxidized and reduced.
- Claim 13 should be rewritten to recite “the dehydrogenase being selected from the group consisting [comprising one] of alcohol dehydrogenase and acetaldehyde dehydrogenase.”
- Dependent claim 14 lacks antecedent basis for “the dehydrogenase.”
- Claim 15 should be rewritten to recite “further including” Same or similar changes in claims 19, 24, 30.
- Claim 16 should be rewritten to recite “being selected from the group consisting of [a group including]” Same or similar changes in claims 20, 22, 28, 33, 35, 36.
- Claim 80 should be rewritten to recite “further comprising [one of] a multivalent transition metal ion or [and] a complex thereof” Alternative language is possible, but the suggested language would be acceptable.
- Similar language change is suggested for claim 81. In addition, “consisting of” should be inserted after “group” in line 2 of claim 81.
- Applicant is advised to rewrite claims 80-82 in independent form, since claim 79 is directed to non-elected subject matter.

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Applicant was advised in the last Office Action as to allowability of vanadyl sulfate/complex + NAD⁺. New claims 42-50 and 52-78 (hereinafter referred to as 42-78) have been submitted; and they require vanadyl sulfate/complex + NAD⁺. The following language corrections are still needed.

Claims 42-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Independent claim 42 recites “one of vanadyl sulfate **and** a complex of vanadyl sulfate” (emphasis added). It would appear that applicant does not intend one of vanadyl sulfate **and** one of a complex of vanadyl sulfate. The language is not clear enough to exclude such interpretation, however. Claim 49 is similarly problematic.

- In claim 43, line 3, “selected from **a** group **including**” (emphasis added) is improper Markush language. Proper Markush language is “selected from the group consisting of ... and” Certain alternative variations in language/terminology are acceptable (e.g., “chosen from ...”), but applicant’s variation is not acceptable as it does not clearly define all of the included Markush members. Claims 52, 58, 59, 78 are similarly problematic.

- In claim 44, “the species comprising one of a group selected from” is similarly problematic. The Examiner suggests --- wherein the species is selected from the group consisting of ... --- .

- Claim 47 should be rewritten to recite “further comprising [also] a base.”

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- Claim 50 should be rewritten to recite "further comprising"
- Claims 52 and claims thereafter should be consecutively renumbered starting from 51.

All dependencies should be changed correspondingly.

- Claim 61 should be rewritten to recite "further including"
- In claim 70, the metes and bounds of "derivatives and analogs thereof" is unclear.
- Claim 72 should be rewritten to recite "further including"
- In claim 74, line 2: "of" should be inserted after "1%".
- Antecedent basis is lacking for "the dehydrogenase" in claim 74.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vadgama et al. (WO 98/20332) for the reasons of record.

Vadgama et al. explicitly disclose a solution mixture of potassium ferricyanide + NAD⁺ (Pages 9-10, Examples 2 and 3).

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive. Applicant's argument regarding the claim language "in the absence of a

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dehydrogenase" is in conflict with applicant's own claim interpretation. Dependent claims 12-14 actually require a dehydrogenase. Therefore, applicant is presumed to be interpreting the above quoted claim language to not have any excluding effect. The cited reference is therefore still deemed to be applicable in light of applicant's own claim interpretation, as evidenced by claims 12-14.

Claims 1-2, 4-11, 15, 17-19, 22-23 and 34-35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Blass (US 5,053,396) for the reasons of record.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive. Applicant asserts that iron ions and chromium ions in Blass' composition would be reduced by ascorbic acid, and thus would not exist in the ion or complex ion state. First, applicant's argument is completely speculative since there are other components in Blass' composition such as sodium bicarbonate, calcium carbonate, zinc and manganese, which may neutralize the ascorbic acid. Second, applicant's argument is not consistent with applicant's own claims. For example, applicant's claims permit the presence of other antioxidants such as isoflavanoids (claim 21). Such compounds would have a similar effect as ascorbic acid, but they are still included in applicant's invention. Therefore, applicant's argument is not persuasive. Applicant's composition is open to various other ingredients, and their complex interaction with other multiple ingredients within the composition is not certain enough to exclude Blass' composition from consideration herein. This ground of rejection is thereby maintained.

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Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Crans et al.


Crans et al. explicitly disclose an analytical grade solutions of a vanadate and NAD, i.e. NAD+.

While it is recognized that the disclosed composition is not expressly disclosed as a composition for accelerating in vivo oxidation of alcohol, the same composition is nonetheless disclosed. And it is the composition per se that is being examined here. There is nothing about Crans' compositions that would preclude it from being capable of functioning as applicant intends. The same two composition ingredients are present, NAD+ and vanadium ion/complex. Analytical solutions for NMR study are typically ultra pure, and such solutions are safe enough for in vivo administration. Therefore, the properties recited in applicant's claims must necessarily be present in the composition explicitly disclosed by Crans et al. The claims are thereby anticipated.

For these reasons, no claim can be allowed at this time.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600